

EFFICACY OF THE STRETCH BAND ANKLE TRACTION TECHNIQUE IN THE TREATMENT OF PEDIATRIC PATIENTS WITH ACUTE ANKLE SPRAINS: A RANDOMIZED CONTROL TRIAL

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ABSTRACT

Background: Ankle injuries account for up to 40% of all sport related injuries. These injuries can result in weeks to months of missed sport or work. The PRICE (Protection, Rest, Ice, Compression, Elevation) treatment is standard care for most acute ankle sprains. Recently, early mobilization in adults has been shown to decrease time off from sport or work, and the likelihood of developing chronic instability. To date, no research has been performed assessing the effectiveness of early mobilization in pediatric patients (<18 years). Purpose: There were two objectives of this study: (1) to determine if early ankle joint mobilization using elastic band traction is effective and (2) assess the occurrence of adverse events with this technique in the pediatric population.

Methods: Patients with an acute ankle sprain of <7 days referred to physical therapy were randomly assigned to receive early mobilization or PRICE. Early mobilization was performed using a stretch band ankle traction technique. Both groups received a standardized rehabilitation program. Pain, edema, ankle strength using hand-held dynamometry, and Foot and Ankle Disability Index (FADI) were measured at both initial evaluation and at discharge. The number of days before return to sport and the number of treatment sessions were also variables of interest.

Results: Forty-one pediatric patients were recruited for participation (mean age 14.6 + 1.9 years). Both treatment groups had clinically significant improvements in pain, edema, strength, and FADI scores. No significant differences in outcomes were noted between treatment groups. Mean number of days for return to sport for the PRICE group was 26.33 + 7.14 and the early mobilization group was 26.63 + 14.82, the difference between groups was not significant ($p = 0.607$). The number of total visits for the PRICE group of 8.07 + 2.63 and the early mobilization groups of 8.5 + 1.57, was also not statistically significantly different ($p = 0.762$). There were no reported adverse events with early mobilization.

Conclusion: Early mobilization appears to be a safe intervention in pediatric patients with an acute ankle sprain. Early mobilization resulted in similar outcomes when compared to traditional PRICE treatment. A high drop-out rate in both treatment groups was a limitation of this randomized trial.

Level of evidence: 1b

Key words: Ankle sprain, pediatric, mobilization

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INTRODUCTION

Ankle sprains are the most common acute injuries sustained in sports with approximately two million occurring annually in the United States.^{1,2} Ankle sprains account for 40% of all sports related injuries.³ Lateral ankle sprains specifically account 85% of all ankle sprains.^{3,4} Up to a third of lateral ankle sprains can become chronic injuries with persistent pain, swelling, and limitation of activity.⁵ Injuries such as these lead to lost time on the playing field and decreased ability to function in school and work.^{1,2} Medical costs associated with ankle sprains have been estimated at \$3.65 billion.² Thus, it is imperative to try to speed the recovery time associated with these injuries in order to both decrease medical costs and enhance return to function.

The current standard of treatment for acute ankle sprains continues to be defined by the acronym PRICE (protection, rest, ice, compression, elevation).^{6,7} However, more recent evidence supports the supposition that early movement will hasten recovery as compared to rest.^{8,9} Some of the benefits of early movement for acute injuries include earlier return to work, decreased pain, swelling, and stiffness, and greater preserved joint motion.⁸ Pain perception has also been shown to decrease 24 hours after mobilization for lateral ankle sprains.¹⁰ Furthermore, early movement does not increase ligament laxity or prolonged symptoms.⁸

Manual therapy consisting of a combination of joint mobilization and manipulation has been found effective for treating acute ankle sprains in adults.¹¹ Adults with acute first-time ankle sprains treated with early mobilization report more comfort and earlier return to work than adults treated with immobilization.¹² Both mobilizations with movement and talocrural mobilization safely lead to increased dorsiflexion motion.^{13,14} Talocrural mobilizations lead to fewer treatments and improved stride speed as well.¹⁴ Joint mobilization and clinic supervised exercise provides better improvements in pain and function when compared to a home exercises program.⁴

Although early joint mobilization is effective in adults, studies have not assessed the efficacy or safety of early mobilization for pediatric patients (≤ 18 years) with lateral ankle sprains. This study examined return to sport times for patients who receive early mobilization

verses the traditional treatment PRICE, as well as use a technique that could be replicated at home independently in areas where access to physical therapy services maybe limited. Therefore, the two objectives of this study were: (1) to determine if early ankle joint mobilization using elastic band traction is effective and (2) assess the occurrence of adverse events with this technique in the pediatric population.

METHODS

The design of this study was a single blinded randomized controlled trial using a sample of convenience. Patients presenting to Nationwide Children's Hospital sports medicine or physical therapy clinics in Columbus, Ohio with an acute lateral ankle sprain were eligible for participation. Patients were diagnosed with acute lateral ankle sprains by the sports medicine physician. This study was registered at ClinicalTrials.gov (Identifier number NCT01134653). The institutional review board approved this study prior to recruitment and data collection. Inclusion criteria were; patients 8-18 years old, with an acute lateral ankle sprain of < 3 days. The inclusion criteria of duration of ankle sprain was later modified from 3 days to 7 days due to recruitment difficulties. Patients were excluded if they had a: latex allergy, syndesmotic ankle sprain, concurrent lower extremity injury, previous history of lower extremity surgery or fracture in the past year, inability to follow directions, and inability to attend follow-up appointments. After the parent or legal guardian and patient gave informed consent/assent and prior to randomization, the patients were evaluated by a physical therapist. Pre-treatment evaluation measures included clinical and self-report measures. These same evaluation measures were completed at discharge by a different blinded therapist.

CLINICAL MEASURES

Figure Eight Tape Measurement of Ankle Edema-

Ankle and mid-foot edema was measured using the figure-of-eight procedure described by Esterson¹⁵ and modified by Petersen.¹⁶ This is performed by using a flexible tape measure with the zero point positioned in the groove at the edge of the lateral malleolus, approximately midway between the prominence of the tibialis anterior tendon and lateral malleolus. The

tape measure was then drawn medially across the instep, pulled toward the base of the fifth metatarsal, drawn toward the medial malleolus and across the Achilles tendon to the lateral malleolus, and finally brought around to meet the original zero. All measurements were rounded up to the next whole millimeter. The amount of edema was reported as the difference between the injured and uninjured figure-of-eight measurements.

Numeric Pain Rating Scale (NPRS)

The NPRS is an 11-point pain-rating scale ranging from 0 (no pain) to 10 (worst imaginable pain) used to verbally assess current pain intensity as well as the best and worst level of pain during the last 24 hours.¹⁷ A score of ± 2 represents the minimal clinically important difference.¹⁸

Ankle Range of Motion (ROM)

Both active and passive motion of dorsiflexion, plantarflexion, inversion, and eversion was measured using a standard 8" goniometer with the patient in the supine position.¹⁹

Ankle Muscle Strength

Strength was measured using a digital hand-held dynamometer for dorsiflexors, plantarflexors, invertors, and evertors. Testing was performed using a make-test, with the patient in the long sitting position. Repeated strength measurements were performed for three sequential tests, the highest of the trials for each motion was recorded.

SELF-REPORT MEASURES OF FUNCTION

Foot and Ankle Disability Index (FADI) and FADI Sport Module-

The FADI is a 26-item questionnaire that uses a 5 point scale ("unable to do" through "no difficulties at all") to rate the extent that the ankle injury in impacting everyday life.^{20,21} Items include a variety of activities from standing and sleeping through stair climbing and recreational activities. The FADI sport modules includes an additional 8 items related to specific athletic movements such as landing and cutting, questions about the technique and duration of participation. The FADI has been shown to have excellent construct validity ($r = 0.64$) and excellent intra-rater reliability.²¹ The

FADI has a reported minimal detectable change (MDC) of 4.8 points.²²

Interventions

After the evaluation, the patients were randomly assigned to either traditional PRICE treatment or early mobilization. The therapist that completed the evaluation then performed the assigned treatment. The evaluation measures were performed before group assignment to maintain blinding during data collection.

PRICE group

Patients randomized to the PRICE group were instructed in ankle compression wrapping if they had not already been issued a lace-up ankle brace. If issued a lace up ankle brace by their physician, the brace provided compression. Patients were instructed to wear compression during weight-bearing activity and at least eight hours a day. During the first 72 hours these patients were instructed to rest, use intermittent ice and compression, as well as elevate their sprained ankle at least 12 inches while lying in supine. Patients were instructed to remove their brace to ice and elevate their ankle for 20 minutes, two times a day.

Early Elastic Band Mobilization Group

For the early elastic band mobilization group, the talocrural distraction technique described by Hartzell and Schimell²³ was followed. Two mini Jump Stretch® bands (JumpStretch Inc. Stow, Ohio) were looped around the patient's shoe, so that the center of distraction pull was directly inferior to the talocrural joint. (Figure 1) The therapist used these bands to put as much horizontal traction on the ankle joint as possible without creating pain. The patient then actively dorsiflexed and plantarflexed the ankle within pain free ROM for 30 seconds or until fatigue with the aim of increasing pain free talocrural motion. After a 30 second rest, the patient actively inverted and everted their ankle within pain free ROM for 30 seconds or until fatigue. The traction force was then released and the patient actively performed 10 clockwise and counter-clockwise circles. The band traction was then repeated in a vertical traction position, as this position is thought to help reduce edema. (Figure 2) After an additional 30 second rest, a third light Jump Stretch® band was



Figure 1. *Horizontal Elastic Band Traction.*



Figure 3. *Horizontal Elastic Band Traction with Overpressure Setup.*

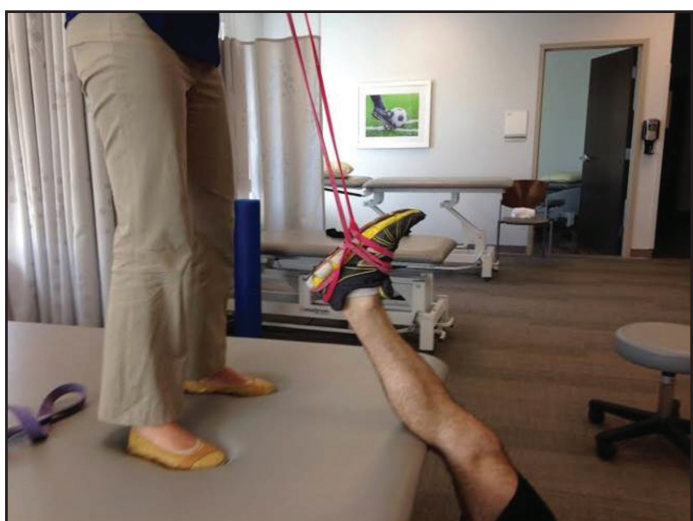


Figure 2. *Vertical Elastic Band Traction.*

placed around the patient's metatarsal heads with the end of the band held by the patient. (Figure 3) The patient pulled on the band while the therapist provided horizontal traction at the ankle. This additional band around the metatarsals allowed the patient to add pain-free plantarflexion resistance while the therapist provided talocrural distraction. The patient then actively dorsiflexed and plantarflexed their ankle for 30 seconds or until fatigue. With the bands in the same position this procedure was repeated with the patient performing inversion and eversion motion.

If patients receiving elastic band mobilization were issued an ankle brace from their physician, they

could continue to wear the brace as desired. The patients were instructed not to ice or perform compression or elevation in this treatment group.

Standard physical therapy care

A standard treatment program was administered for both groups according to prescribed progression criteria (Appendix 1). There were three Phases in the standardized treatment program and the patient transitioned through each Phase based on functional ability. All patients began with Phase 1 and transitioned to Phase 2 once they demonstrated: 1) no gross deviations with walking, 2) a report of < 5/10 pain with ADLs on the NPRS, and 3) within 5 degrees of ROM to the contralateral ankle for all planes of motion. Patients transitioned from Phase 2 to Phase 3 once they were able to demonstrate: 1) single leg balance on the injured lower extremity >30 seconds, 2) up and down 12 stair steps using a reciprocal gait pattern without pain, 3) able to jog for 2 minutes on the treadmill with < 2/10 pain and 4) no report of instability with gait.

Patients were discharged from physical therapy once they completed all 3 Phases of standard therapy and were able to meet the following functional criteria: 1) single leg hop test within 80% of the contralateral limb, 2) Ability to single leg balance within 2 seconds of uninvolved lower extremity on an inflated rubber hemisphere attached to a rigid platform (BOSU). The number of days from initial evaluation until the patient met the discharge criteria was recorded for the outcome of time in therapy.

BLINDING AND RANDOMIZATION

The evaluating therapist was aware of treatment allocation, whereas the exercise therapist and discharge therapist were blinded to treatment group allocation. Due to the nature of the intervention, blinding patients to treatment allocation was not feasible. Randomization was determined by sealed envelopes which were opened by the evaluating therapist after the patient agreed to participate and evaluation measures had been completed. An individual not involved in the study filled 50 blank envelopes with a paper designating either Jump stretch or PRICE. The envelopes were shuffled and given a numeric number from 1-50. When patients were enrolled the next numeric envelope was opened and the patient received the treatment described on the paper.

SAFETY

To address the issue of safety, patients who experienced a clinically significant increase in pain (MCID of two points), which did not affect their ability to perform activity, during or after the elastic band traction were classified as having had a mild adverse reaction. Following the treatment, if patients reported or were observed to have a decrease in their ability to perform activity they were classified as having had a moderate adverse event. Patients were instructed that if they experienced pain or reduced function following the intervention to notify study staff. Patients who had an adverse reaction were re-evaluated by their therapist. The patient would be referred back to their physician if they demonstrated a significant injury or were deemed inappropriate to continue physical therapy.

SAMPLE SIZE

The calculations were based on detecting an 4.6% difference in the FADI index at the 4-week follow-up, assuming a standard deviation of 5.1, a 2-tailed test, and an alpha level equal to 0.05 and 80% power.^{22,24} This generated a sample size of 18 patients per group. Allowing for a conservative dropout rate of approximately 15%, we recruited 41 patients into the study.

DATA ANALYSIS

All analyses were conducted using SPSS 21 software. An intent-to-treat design with the multiple imputation model was used for any missing values. The first aim

of the study was examined with a two-way repeated measures multivariate analysis of variance (MANOVA) with treatment group as the between-patient variable and time (baseline, and discharge) as the within-patient variable. The dependent variables were function (FADI and FADI sport score) and pain. The relative risk of having an adverse reaction from early mobilization was calculated to assess the second aim of this study. A Chi-square analysis was performed to determine if there were any differences between treatment groups for adverse reactions. Post-hoc repeated measure univariate analyses were performed to assess the individual effect of the intervention on FADI, FADI sport, and pain. Secondary outcomes including edema, range of motion, and strength were assessed using a t-test or Wilcoxon rank sums test depending on the nature of the data distribution.

RESULTS

Eligible participants were recruited from March 2010 to February 2014. Study staff screened 1,970 consecutive patients who presented to the sports medicine physicians or physical therapists with an ankle sprain for inclusion. Forty-one patients (aged 10-18 years) were enrolled after receiving written consent from the patients and their parent or legal guardian (Figure 4). All patients received the appropriate randomized treatment intervention (early elastic band mobilization or PRICE).

Baseline variables were similar between treatment groups. (Table 1) Eleven patients dropped out of physical therapy before discharge (eight in the early elastic band mobilization group and three in the PRICE group). All patients reported non-study related reasons for not continuing with physical therapy treatment (time and financial constraints). A grade II lateral ankle sprain was the most common referring diagnosis for patients participating in this study (71%), with grade I lateral ankle sprains accounting for 24% and Grade III 5% of injuries. There were no significant differences in grade of sprain between treatment groups ($p = 0.89$).

Patients in both groups were treated for an average of 7.7 ± 3.8 visits over the course of 25 days to meet all predetermined discharge criteria. (Table 2) Between-group comparisons revealed no significant differences in the number of visits or duration of

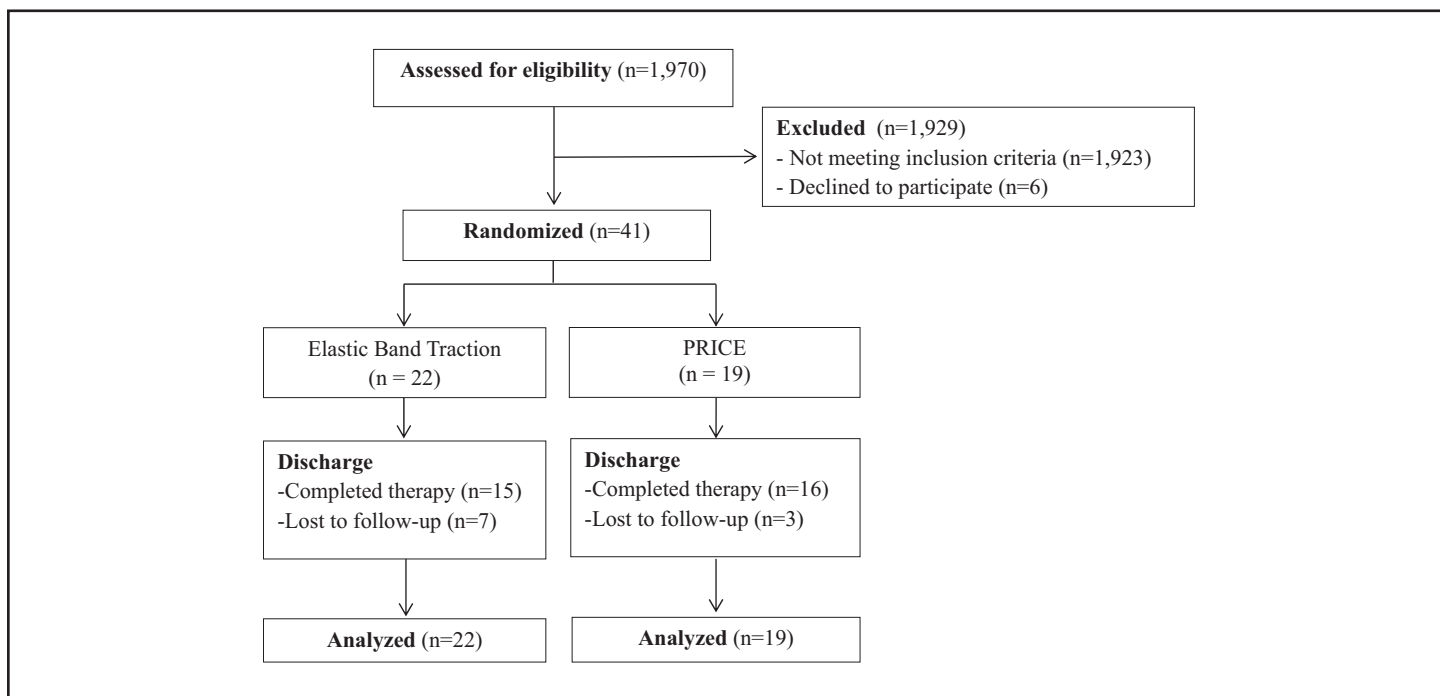


Figure 4. Flow diagram for patient recruitment and randomization.

Table 1. Baseline Demographic and Self-Reported Values. Data reported as mean (SD) or numbers (%).

	All Patients (n = 41)	Elastic Band Traction (n = 22)	PRICE (n = 19)
Age (years)	14.5 ± 1.8	14.9 ± 1.8	14.2 ± 2.0
Sex (% female)	19 (46%)	12 (55%)	7 (37%)
Days since injury	4.7 ± 1.8	4.4 ± 1.9	5.2 ± 1.5
Pain (NPRS)	4.9 ± 2.4	5.1 ± 2.7	4.7 ± 2.2
FADI	64.9 ± 22.8	66.1 ± 25.5	63.4 ± 20.1
FADI Sport	8.6 ± 10.1	9.3 ± 10.6	7.8 ± 9.8
Edema- Figure of eight (cm)	1.7 ± 1.2	1.9 ± 1.3	1.4 ± 1.1

PRICE = Protection, Rest, Ice, Compression and Elevation; FADI = Foot and Ankle Disability Index

Table 2. Pairwise comparison of treatment session and duration of care.

	All Patients (n = 41)	Early Elastic Band Mobilization (n = 22)	PRICE (n = 19)	p- value
Treatment Sessions	7.7 ± 3.9	8.0 ± 4.6	7.3 ± 2.9	0.61
Total Days of Care	25.3 ± 12.3	25.2 ± 14.9	25.5 ± 9.0	0.95

care. Both groups had significant decreases in edema at discharge ($p < 0.01$). Early elastic band mobilization group had a mean of 0 ± 0.6 cm of edema and PRICE had a mean of 0.1 ± 0.4 cm of edema compared to the non-injured ankle. There were no significant differences between treatment groups

($p = 0.77$). Dynamometer strength testing of the injured ankle showed significant weakness, $< 90\%$ of compared to uninvolved limb, in all major motions (Table 3). Both groups demonstrated significant increases in strength at discharge ($p < 0.01$) but there were not significant differences between treatment groups.

Table 3. Ankle strength, measured using handheld dynamometer (kg).

	All Patients (n = 41)		Elastic Band Traction (n = 22)		PRICE (n = 19)	
	Baseline	Discharge	Baseline	Discharge	Baseline	Discharge
Dorsiflexion	7.7 ± 4.3	15.8 ± 4.9	7.6 ± 4.3	16.0 ± 4.5	7.8 ± 4.4	15.5 ± 5.4
Plantarflexion	15.5 ± 7.0	27.4 ± 6.7	16.6 ± 6.9	28.7 ± 5.7	14.2 ± 7.0	26.2 ± 7.5
Inversion	5.0 ± 2.5	9.9 ± 3.5	5.0 ± 2.7	11.2 ± 3.1	5.1 ± 2.4	8.6 ± 3.5
Eversion	4.3 ± 2.6	9.4 ± 2.6	4.4 ± 2.7	10.5 ± 2.1	4.3 ± 2.6	8.4 ± 2.6

The two-way treatment group x time interaction repeated measures MANOVA demonstrated no statistically significant between-group differences for function and pain ($p = 0.79$). Within-group differences showed that both groups had statistically and clinically significant improvement at discharge. Repeated measures univariate ANOVA demonstrated no differences between treatment groups for function or pain (Table 4). No patient in either group reported an adverse reaction with treatment. Relative risk and chi-square analyses were not performed since no adverse reactions were noted.

DISCUSSION

Joint mobilization has been shown to be effective for improving function and increasing motion in adults and older adolescents with ankle injuries. This study assessed the safety and efficacy of early manual joint mobilization after an acute inversion ankle sprain in pediatric patients as young as 10 years of age with a mean age significantly younger than subjects of any other study. No adverse events were noted with the use of elastic band ankle traction mobilization in this study. Although some authors have voiced concern over performing joint mobilization techniques in pediatric patients due

to concern of growth plate injury there have been no documented cases of a growth plate injury as a result joint mobilization. Additionally, the forces imparted from mobilization are significantly lower than those that children experience during commonly performed activities.²⁵⁻²⁷ The results of this study offer preliminary evidence that early ankle joint mobilization is safe in this population. This finding is consistent with other research assessing joint mobilizations to the lumbar spine in pediatric patients.^{28,29}

Many studies performed on adults have focused on short-term results of manual therapy with follow-up times from immediate to one-week.^{10,14,30,31} The authors chose to look at longer term outcomes, including time to recovery, and change in the function and pain at discharge from supervised therapy. Cleland et al.⁴ assessed the long-term outcomes (four-week and six-month) of joint mobilizations compared to a supervised home exercise program for acute lateral ankle sprains. Although significantly better outcomes were found with joint mobilization, Cleland's study assessed joint mobilization and supervised exercise compared to a supervised home exercise program. Due to their study design, it

Table 4. Pairwise comparison of Function and Pain.

		Baseline	Discharge	P value	Mean Difference (95% CI)
FADI	PRICE	63.4 ± 20.1	101.6 ± 2.8	0.49	3.0 (-5.9, 12.0)
	Elastic Band Traction	66.1 ± 25.5	102.1 ± 2.7		
FADI Sport	PRICE	7.8 ± 9.8	29.1 ± 3.1	0.09	3.2 (-0.5, 7.0)
	Elastic Band Traction	9.3 ± 10.6	30.6 ± 2.0		
Pain (NPRS)	PRICE	4.7 ± 2.2	0.1 ± 0.3	0.98	-0.01 (-1.0, 1.0)
	Elastic Band Traction	5.1 ± 2.7	0.1 ± 0.3		

is difficult to conclude the addition of joint mobilization was solely responsible for the positive long-term outcomes. The design of the current study allowed for the assessment of the mid-term efficacy of the addition of a manual therapy technique to a supervised exercised program. The results of the current study show, at least for the pediatric population, the addition of early joint mobilization to a supervised exercise program was not more beneficial than traditional PRICE recommendations.

The results of the current study indicate that the addition of talocrural distraction to a supervised PT program was not more effective than PRICE followed by supervised PT. These results contrast with findings from similar research in the adult population; there are several possible reasons for the conflicting evidence.^{4,10,14,30} The first possible reason is that children recover well following an acute ankle sprain and the addition of manual therapy may not be needed. Another reason for the conflicting results may be the lack of a short-term assessment in the current study. Studies of adults demonstrate positive short-term results, however, it is unknown if children might experience a similar short-term benefit.^{10,14,30,31} Finally, this study assessed elastic band ankle traction with movement at the talocrural joint, which is a different technique for joint mobilization than what has been previously shown to be effective in an older population.^{4,10,14,30} There were two reasons the authors chose this technique: 1) Distraction manipulation of the talocrural joint has been shown to have positive results in adult research, but a mobilization technique was chosen as the safer alternative for the pediatric population, and 2) with minor modification and instruction, the patient can perform the elastic band ankle traction technique independently (as a self-mobilization).

LIMITATIONS

There are a number of limitations to the current study that should be considered. First, there was a high drop-out rate noted in both treatment groups (24%). Second, there were difficulties recruiting patients who met the original strict acute injury inclusion criteria. The authors lengthened the time post-injury from 3 to 7 days in an attempt to increase the number of patients eligible for this study. By altering the inclusion criteria to improve recruitment,

time to early joint mobilization was delayed. This delay in application of the joint mobilization may have altered its effectiveness for improving patient outcomes. Additionally, this study only assessed one distraction joint mobilization technique to the ankle, whereas positive responses in adults resulted from multiple joint mobilizations to both the ankle and knee.⁴ A more expansive joint mobilization approach may have produced different results.

CONCLUSIONS

Early mobilization appears to be a safe intervention in pediatric patients who have sustained an acute ankle sprain. Early mobilization resulted in similar outcomes in pain, range of motion, and self-reported function when compared to traditional PRICE treatment. A high drop-out rate in both treatment groups was a limitation of this randomized trial.

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Appendix 1

Phase I

Ankle alphabet (A-Z x 1)

Gastrocnemius stretch against wall (3 x 30 seconds)

Soleus stretch against wall (3 x 30 seconds)

BAPS® seated: Level 2 if children shoe size (up to size 13.5) , Level 3 if adult shoe size (30 repetitions each)

-dorsiflexion/plantarflexion, inversion/eversion, clockwise and counter clockwise circles

Elastic Band 5-way ankle strengthening. (15-30 repetitions)

-dorsiflexion, plantarflexion knee straight, plantarflexion knee bent, inversion, and eversion.

Straight leg raises abduction and extension (30 repetitions)

Seated heel and toe raises (30 repetitions)

Weight Shifts anterior/posterior (20 repetitions)

Weight Shifts Lateral (20 repetitions)

Phase II

Treadmill walk at 2.5 mph (3-5 minutes based on tolerance)

Treadmill light jog at 5.5 mph (30 seconds -2 minutes based on tolerance)

Treadmill side step away from injury (3-5 minutes)

3-way medicine ball toss (1kg) at rebounder in single leg stance. (15 repetitions each direction facing with rebounder to the front, left and right)

Standing elastic band resisted hip three-way (hip flexion abduction and extension) (15-30 repetitions)

Functional Star: Stand on single leg. Opposite lower extremity reaches in five directions hold at the end of the reach for 2 seconds. Start with five repetition and progress to 10.

Calf raises (15-30 repetitions)

Squats (15-30 repetitions)

Half foam roll dorsiflexion (15-30 repetitions)

Lateral step downs (15-30 repetitions, step height based on patient)

4-way resisted walking: One inch medium elastic band placed around patients' waist and the opposite end anchored to the wall. (x 5 repetitions each: Forward, Backward, Lateral Left, Lateral Right)

Appendix 1 (continued)

Phase III

Treadmill running at 6 mph (up to 10 minutes -slow down or stop if Pain > 3/10)

1 foot to 2 feet hops in place (20 repetitions)

2 feet to 1 foot hops in place (20 repetitions)

Line jumps forward/backwards and side to side (2-3 repetitions of 30 seconds each)

Carioca (4 repetitions of 30 feet)

Single leg diagonal hops for distance (5 repetitions)

Shuttle run drill (20 feet distance down and back, 5 repetitions)

BOSU® runs forward (2 repetitions of 30 seconds)

BOSU® runs lateral (2 repetitions of 30 seconds)